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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,518	11/16/2001	William Fenical	6627-PA1022	7755

27111 7590 09/15/2003

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

13

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,518

Applicant(s)

FENICAL ET AL.

Examiner

Irene Marx

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The application should be reviewed for errors.

In keeping with scientific custom, the names of genera, classes or families of microorganisms should be capitalized and italicized or underlined, such as *Actinomyces*.

Applicant's election with traverse of Group I, claims 1 and 13-20 in Paper No. 12 is acknowledged. The traversal is with respect to Groups I and II only, on the ground(s) that because a search for group I would identify art "relevant" to the methods of claims 2-7 and 18-20 the groups should be rejoined.

However this is found persuasive only with respect to claims 13-20. This argument is not found persuasive with respect to claims 2-7 because the method of groups II is of a different scope from the composition of group I and the references which would be applied to group I would not necessarily anticipate or render obvious the other group.

Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exists.

Clearly different searches and issues are involved with each group.

For these reasons, the restriction requirement is deemed proper and is adhered to. The restriction requirement is hereby made FINAL.

Claims 2-12 are withdrawn from consideration as directed to non-elected inventions.

The attempt to incorporate subject matter into this application by reference to sequences deposited in GenBank is improper because this is essential material required for the proper examination of the present specification and claims. In order to carry out a meaningful search of the claims the precise material intended to be incorporated must be provided in the instant application and in proper format.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1 and 13-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for "18S rRNA" as recited in claim 1.

No basis or support is found in the present specification for a *Salinospora* having an adenosine at position 1456 of the 16S r RNA as now recited in claim 13. See, e.g, Table 3, Specification, page 12..

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in the recitation of certain positions in the 16S rRNA or 18r RNA without an indication of the context of these positions. The intended sequences must be in the specification and/or claims in proper form for examination and be properly identified.

Claims 14-16 are indefinite in the recitation of GenBank entry numbers. Revisions or updates to GenBank entries can be made at any time. The interpretation of a claim that refers to a GenBank entry is dependent upon the particular revision, update or release date of that particular entry. The metes and bounds of the claim(s) are not clearly set forth.

Also, the claim does not comply with the sequence rules. Moreover, there is improper incorporation by reference, as noted. Since GenBank accession numbers may not change when GenBank sequences are amended, one would not know the precise nucleic acid sequences associated with the accession numbers at the time the application was filed. If the GenBank listings are in fact incorporated by reference (mere reference to a publication is not an incorporation of anything into the application), applicant is required to amend the specification to

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include the sequences incorporated by reference because the sequences are essential material. See MPEP 1 608.01(p). Applicant must establish that the sequences added by amendment are the sequences present in the GenBank data base as of the filing date of the application. This is because if GenBank sequences are amended and accession numbers do not change, the metes and bounds of the invention may change. A sequence previously meant to be excluded at filing may no longer be excluded, or a sequence not previously meant to be excluded may become excluded.

If applicant chooses to amend the specification by inserting the sequences corresponding to the accession numbers, the inserted sequences must comply with the sequence rules. Of course in order to make such an amendment without introducing new matter, applicant must establish that the inserted sequences were identical to those in the GenBank listings as of the filing date of the application.

Claim 17 is confusing in that it is uncertain what is intended by "sediment-derived" in this context, since it is unclear whether the bacterium is derived by chemical, physical or biological means. Amendment to -- obtained from-- would be remedial.

Claims 19 and 20, are method claims, improperly dependent on claim 13, a product claim. Claims 19 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 19 is internally inconsistent and/or incorrect in the recitation "the biomolecules is".

Claim 18 is vague and indefinite in that it is unclear whether the extracted "biomolecule(s)" are produced by the strain or whether they are obtained from the original, uninoculated culture medium.

Claims 1 and 13-18 appear allowable over the art because marine *Actinomycetes* of the genus *Salinospora* are novel and non-obvious over the art of record. There would have been no motivation for one of ordinary skill in the art to modify the processes of the prior art relating to the production of biomolecules by culturing microorganisms of this genus in the manner claimed.

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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.



Irene Marx
Primary Examiner
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